Does Reducing Product Liability Affect Market Value?

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ABSTRACT

I investigate whether shielding manufacturers from product liability affects their market values. Using the vaccine industry as an example, I examine events surrounding the introduction of the U.S. National Childhood Vaccine Injury Act (NCVIA), legislation that protected vaccine firms from product liability. The market reacted negatively when courts enforced liability. Examining 133 new vaccine approvals, I find the market awarded the licensing of a new vaccine in the United States 1.3% higher after NCVIA compared with before the legislation, when the market was indifferent to the announcement of a new vaccine. Results suggest that preempting product liability litigation can contribute to transforming a low-profit business into an attractive product line.

INTRODUCTION

"The ['vaccines court'] …buffers…makers of childhood-disease vaccines from much of the litigation risk that dogs traditional pill manufacturers and is an important reason why the vaccine business has been transformed from a risky, low-profit venture in the 1970s to one of the pharmaceutical industry's most attractive product lines today" (Wall Street Journal, 2009).

Scholars have long regarded regulation and litigation as complements (Kolstad, Ulen and Johnson, 1990). Ex ante regulation sets a minimum standard of care, while ex post litigation forces companies to make costly changes to address unforeseen problems with their products. Although several examples of preempting regulation (deregulation) exist – including telecommunications, transportation, and banking – we know very little about the preempting of litigation or "delitigation." Theoretically, if a firm is able to preempt litigation, the firm's market value could either remain constant or increase. Market value would not change if the regulator takes over the role of litigation by enforcing more oversight ex post, because no major change would occur in the manufacturing process. Regulators would force firms to continue to monitor and to address unforeseen problems. Market value would also not change if the producer passes savings in litigation costs onto the consumer by lowering prices. Conversely, if the regulator does not increase ex post oversight to the ex ante level and the firm does not lower its prices, the market value of the firm should increase. The market would react positively to delitigation both at the time of announcement

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as well as subsequent announcements of new products, since the firm could manufacture the new products more cheaply.

We can view the passage of the U.S. National Childhood Vaccine Injury Act (NCVIA) in 1986 as a social experiment to examine the effect of delitigation on firm value. The Act established the Vaccine Injury Compensation Program (VICP), a U.S. government program that shields vaccine manufacturers from most product liability litigation. If a vaccine injures a person, he or she can file a claim under VICP to receive compensation. Funding for the Program comes from an excise tax on the sale of each vaccine. Examining market responses to events before and after the passage of the legislation provides insights into the effects of delitigation.

To evaluate the influence of delitigation, I examine changes to vaccine manufacturers' equity values around events associated with the introduction and implementation of product liability preemption. I find that vaccine manufacturers in the United States experienced negative returns when a U.S. court found a firm liable for vaccine injury. I also find the licensing of a vaccine in the United States is more valuable to a firm after the passage of limited liability than before. Prior to the legislation, the announcement effect of the licensing of a new vaccine was, on average, zero; after delitigation, pharmaceutical companies earned on average a statistically significant 1.1% when they announced a new vaccine. Taken together the results suggest delitigation has helped to transform vaccines into attractive products.

POLICY IMPLICATIONS OF DELITIGATION

The findings of this study have implications in several areas of public policy. Governments are often major purchasers of vaccines, and reducing litigation costs could reduce the prices of vaccines. Manning (1994) investigated the influence of changes in tort law on the prices of vaccines. He found that under a regime of strict product liability to the vaccine manufacturer 96 per cent of the price of the DPT vaccine went toward litigation costs. Reducing litigation costs could reduce the cost of producing goods. Firms could lower the prices of vaccines, allowing governments and other consumers to reduce spending. Indeed, when Manning (1997) investigated price differences between prescription drugs sold in Canada versus the United States, he found that half of the difference in price comes from the litigation risk that drug makers experience in the United States that Canadian sellers do not experience.

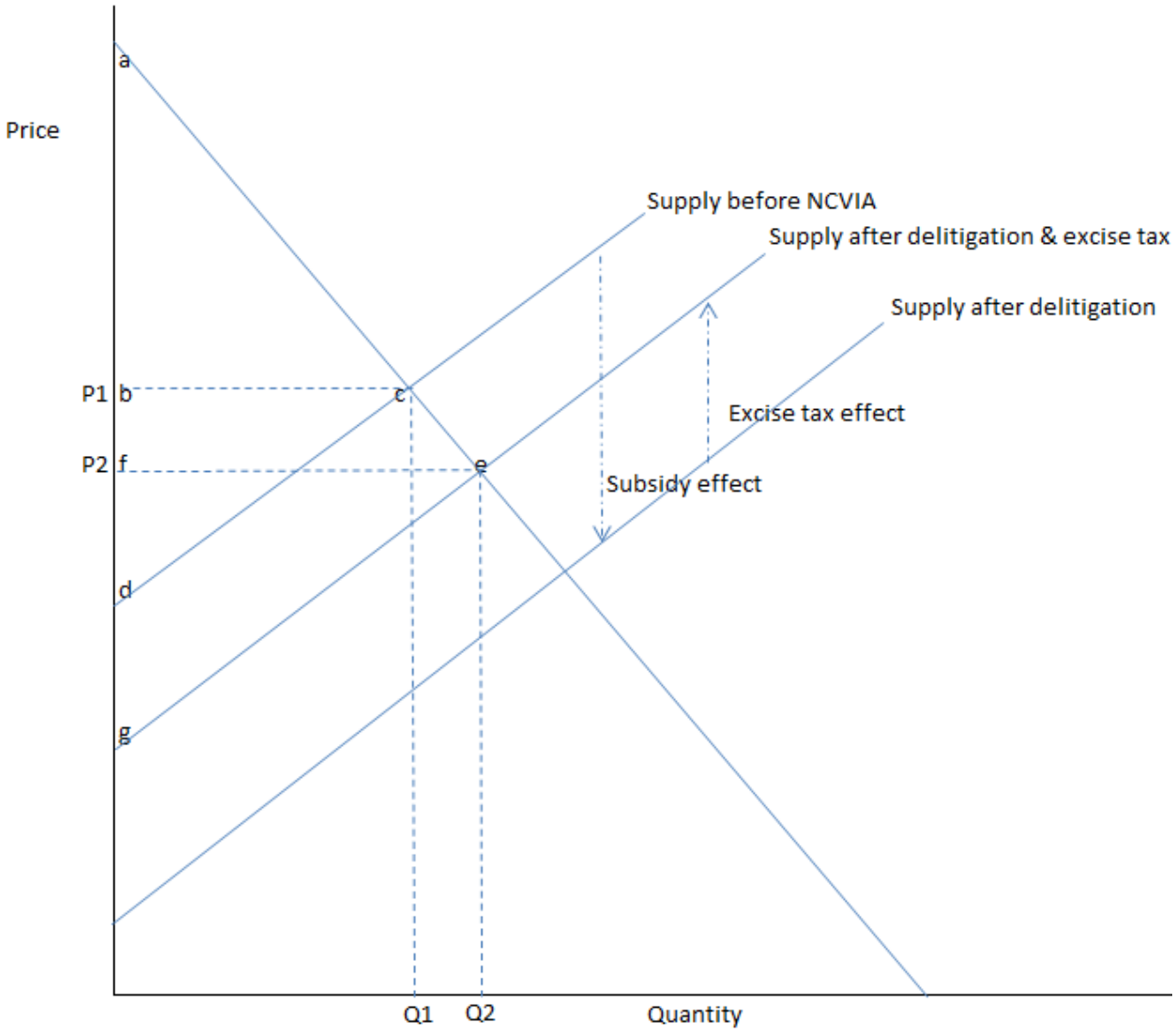
A second issue is the influence of litigation costs on product innovation. Viscusi and Moore (1993) show how large litigation costs can stifle innovation and the development of new products. Although VICP does not address this issue, enhancing product development could be a by-product of lowering litigation costs.

A third important policy issue is the acceptance of childhood vaccines. Public trust is essential for a successful immunization program, yet trust in vaccines is falling (Opel, et al., 2013). Almost half of all parents surveyed expressed concern that the profit motivation biased pharmaceutical companies, thereby

making vaccine information unreliable (ASTHO, 2010). If this research shows no change after delitigation – that vaccines were not and are not particularly profitable – parents might be more trusting of the information they receive about vaccines and be more willing to participate in childhood vaccine programs.

A fourth policy implication involves the influence of NCVIA on economic distortions. By lowering producers' costs of litigation and compensation, NCVIA essentially subsidizes the manufacture of vaccines. However, it uses an excise tax on consumers to defray the costs of the compensation. The following graph shows the net effect of NCVIA on producer and consumer surpluses:

Figure 1: Supply and demand for vaccines before and after NCVIA



The original supply curve ("Supply before NCVIA") intersects the demand curve at point C, suggesting the following free-market equilibrium conditions: price P1, quantity Q1, consumer surplus *abc* and producer surplus *bcd*. VICP addresses two costs to producers, litigation and compensation. The legislation drives the litigation costs close to zero – in effect a subsidy – while shifting the compensation cost of injury to consumers through an excise tax. The curve "Supply after delitigation" depicts the subsidy effect of VICP. "Supply after delitigation & excise tax" shows the effect of the excise tax that compensates injury. The result is a new equilibrium price of P2, lower than the original price, and a greater quantity Q2. As long as prices fall, consumer surplus increases to *afe*. Producer surplus would be *feg*, which is greater than *bcd* as long as the "Supply after delitigation & excise tax" does not return to the original "Supply before VICP." A shift back to the original supply curve would occur only if the excise tax covered all the costs of product injury. However, the excise tax covers only the costs associated with injuries, and not litigation costs. Producer surplus, therefore, also increases.

The preceding analysis suggests testable hypotheses concerning the benefits of VICP to producers and consumers that I explore in this paper. Before presenting the hypotheses, I provide background into product liability and the NCVIA.

WHY PRODUCT LIABILITY IS EXPENSIVE

Product liability is expensive: Firms incur both direct litigation costs as well as indirect costs when a consumer files a product injury case. Bhagat, Bizjak and Coles (1998) find firms lose an average of almost 1.5% of market value upon the filing of product liability lawsuit against them and posit that reputational costs are extremely high for defendants of product liability cases. Viscusi and Hersch (1990) find that product liability litigation influence market returns more than actions by regulators. Firms expressed concerns that additional consumers would file lawsuits or regulators would force the firms to stop a particular line of business or both. Prince and Rubin (2002) find that events leading up to the verdicts can be detrimental to the automotive and pharmaceutical firms they examine. They find a firm loses value upon the filing of product liability lawsuit or upon the announcement of news that could lead to a lawsuit. The loss in market value often exceeds the direct costs of the fines, providing support for Viscusi and Hersch's finding that firms may incur costs beyond the actual lawsuit. The threat of litigation can also curtail some possible business ventures, since the net present value of a project must include estimated legal costs of product liability. If expected litigation costs are high, a product may not be profitable.

DELITIGATION OF THE VACCINE INDUSTRY IN THE UNITED STATES

In 1976, vaccine makers for the first time experienced delitigation. Prior to that year, firms selling vaccines in the United States bought liability insurance for injuries associated with their products from private companies. In the wake of a potential swine flu epidemic in 1976, the U.S. government wanted to

implement a mass vaccination program against the disease. Private insurance companies refused to cover vaccine manufacturers for the flu shot, because the insurers were concerned that the vaccine makers had rushed through the development process. Although the U.S. Food and Drug Administration (FDA) had approved and licensed the swine flu vaccine, private insurers stated the risks from product liability were unknowable (New York Times, 1976b). Vaccine manufacturers warned that they would not be able to provide the vaccine unless they could obtain liability insurance against injuries associated with their product (Wall Street Journal, 1976). In August 1976, the U.S. Congress passed the National Swine Influenza Immunization Program Act (the "Swine Flu Act"), which directed anyone injured by the flu shot to file a lawsuit against the U.S. government and not the vaccine manufacturer or the person administering the shot. The government could then sue any party that it felt had caused the injury (New York Times, 1976a). The legislation did not include any special procedure for evaluating cases of injury from the swine flu vaccine, and people who claimed to be victims of vaccine injury had to try their cases in regular court. The U.S. government became involved in expensive litigation and paid out over $90 million (Grey, 2011).

Vaccine manufacturers lobbied the U.S. Congress to create a no-fault compensation program similar to the Swine Flu Act for victims of injury from all childhood vaccines (Finkelstein, 2004). The manufacturers argued that increasing litigation was making their business climate uncertain and they needed protection from lawsuits to provide a steady supply of vaccines. Grey (2011) reports that Congress wanted to protect the vaccine industry and provide for a speedy resolution for victims of vaccine injury, but did not want to repeat the expensive litigation that resulted from the National Swine Flu Program.

The National Childhood Vaccine Injury Act (NCVIA), which Congress passed in 1986, decreed that consumers could not hold a vaccine manufacturer liable if its product caused damage as long as the manufacturer used FDA-approved procedures. Consumers could still sue if the company did not warn of dangers or did not follow FDA procedures, but such cases are very difficult to prove. The legislation includes the Vaccine Injury Compensation Program (VICP), which directs a person who believes that a vaccine injured him or his dependent to file a petition in the U.S. Court of Federal Claims. A Special Master adjudicates the claim rather than a judge, and – in an effort to speed the process – the legislation suspends the Federal Rules of Civil Procedure and the Federal Rules of Evidence. The Special Master can request documents, but no one else is entitled to discovery.

HYPOTHESES

In my first test, I seek to establish whether product liability is expensive to vaccine makers. I examine the effect of product liability litigation on the market value of vaccine manufacturers for three events. On February 8, 1972, a Texas jury awarded $200,000 to the father of Anita Reyes, a toddler who became paralyzed after receiving a vaccination against polio manufactured by Wyeth. On July 31, 1974, the Fifth Circuit Court of Appeals upheld the jury decision. On April 30, 1984, an Idaho jury found Lederle liable for

an injury and awarded $1.1 million to the parents of an infant who became paralyzed after receiving Lederle's pertussis shot. To gauge the effect on the vaccine industry, I include not only the defendants in the lawsuits, but also all other vaccine firms for which I am able to find data. My first test is therefore whether product liability litigation is associated with a change in market values for vaccine manufacturers.

Next, I explore whether the NCVIA influenced the market value of vaccine manufacturers. I measure market reaction to the licensing of vaccines before and after legislation that reduced product liability. Although the Act allows vaccine manufacturers to enjoy drastically lower liability, the firms also face increased regulatory burdens. The legislation requires federal agencies to maintain the Vaccine Adverse Event Reporting System (VAERS), where health care providers are to report a suspected vaccine injury. Additionally, the excise tax that compensates people injured by vaccines raises the costs of those vaccines. The costs of the increased regulation may offset the benefits of the lowered liability. I therefore test whether legislation that reduces product liability affects market values of vaccine manufacturers.

Finally, reducing liability costs allows firms to charge less. I therefore examine vaccine prices over time to determine whether they fell.

EMPIRICAL RESULTS

To determine whether vaccine manufacturers in general experienced a change in value when courts found Wyeth Laboratories in the early 1970s and Lederle in the mid-1980s liable for vaccine injuries, I examine the market reactions to the legal decisions. Specifically, I first determine firm *i*'s stock return, $R_{it} = \log(1+(P_{it} - P_{i,t-1})/P_{i,t-1})$, where P_{it} is firm i's stock price at time t, as well as the return to the market, $R_{Mt} = \log(1+(P_{Mt} - P_{M,t-1})/P_{M,t-1})$, where P_{Mt} is the market's index time t. I then determine the relationship between R_{it} and R_{Mt}:

(1) $R_{it} = \alpha_i + \beta_i * R_{Mt} + \varepsilon$.

To estimate α_i and β_i, I use daily stock data from 250 to 30 days before the courts announced the decisions. The expected return for stock *i* on day *t* is $a_i + b_i * R_{Mt}$ where a_i and b_i are the estimates of α_i and β_i from equation (1). Any difference between that expected return and the actual return on day *t* is the abnormal return. I then add together the daily abnormal returns to create the cumulative abnormal returns (CAR_i) for each vaccine manufacturer for the 7-day period (t=-5,1) surrounding the announcement of the legal decision:

(2) $CAR_i = \sum_{t=-5}^{1} R_{it} - (a_i + b_i * R_{Mt})$.

Daily stock prices for firms listed on a U.S. exchange as well as the value-weighted market index come from CRSP. I include all publicly traded firms that sold vaccines in the United States for which I could find stock market data from CRSP. I obtain the names of vaccine license holders in the United States from the *Children's Vaccine Initiative,* which reported that in 1972, 18 entities – including 14 commercial firms, three

public health departments, and one university – held licenses to sell vaccines in the United States. By 1984, the number of commercial firms selling vaccines for the U.S. market had fallen to eight. Of the commercial firms, I was able to find stock market information for nine firms in 1972 and five firms in 1984. Firms for which I could not find data were foreign firms for which CRSP did not provide data. Datastream, a database that reports stock prices for non-U.S. firms, did not have data going back far enough for my analysis.

Reaction to litigation was positive on average in the early 1970s, but turned negative by the mid-1970s. I can provide the chart that details individual firm's reaction to litigation upon request. Highlights are as follows: Investors in most vaccine manufacturers found the jury verdict against Wyeth on February 8, 1972 a positive event. The only firm to experience negative reactions was Lederle (-2.4%), which also produced the oral polio vaccine. However, another producer of the oral polio vaccine, Pfizer, experienced a 2.3% gain. The result suggests that investors expected competitors to gain from Wyeth's troubles, perhaps because only Wyeth (and perhaps Lederle) appeared to have quality control issues. Prince and Rubin (2002) also found that when a consumer sued a drug company for product liability, competitors gained market value. However, investors reacted differently on July 31, 1974 to the upholding of the decision by the 5th Circuit Appellate Court. On average, the manufacturers experienced an abnormal return loss of 7.0%, a total of $1.2 billion ($5.3 billion in 2010 dollars). By this point, investors may have begun to suspect industry-wide liability issues. Similar to Bhagat, Bizjak and Coles (1998), who find that the market value loss to defendants far exceeds the amount of any fine, the market value that the firms lost far exceeded the $200,000 fine that Wyeth had to pay. The same negative reaction occurred ten years later. Investors in all but two vaccine manufacturers greeted the jury decision on April 30, 1984 to award plaintiffs $1.1 million for a vaccine injury as bad news. Firms listed on the U.S. market lost an average of 4.3%, which is economically and statistically significant. Perhaps investors in vaccine manufacturers did not continue to follow the pattern found by Prince and Rubin (2002), because the liability of one vaccine began to raise questions of liability risk in all vaccines.

To determine whether firms experienced abnormal returns associated with legislation that reduced product liability, I look at market reaction to the licensing of new vaccines both before and after delitigation. I examine market reaction to the announcements of the U.S. Food and Drug Administration (FDA) licensing new vaccines. Specifically, I examine market reactions to vaccine licenses before the passage of legislation that preempted product liability and compare them to market reactions after the U.S. Congress passed the legislation. I calculate abnormal returns of stocks using the methodology and data described at the beginning of the Empirical Results section. I find the dates of vaccine approvals from several sources. The FDA (2012) website provides a list of vaccines currently approved in the United States. The supporting documents to this website provide the dates of initial approvals. If the supporting documents did not specify the initial approval date, I searched Factiva for news reports of the vaccine's approval. For dates of historic vaccine approvals, I use Appendix H, "Historical Record of Vaccine Product License Holders in the United

States," of a report by the Institute of Medicine (1993). If a firm receives more than one license on a single day, I include that firm and that date only once. I include only the initial licensing of a particular vaccine and not subsequent uses of the same vaccine. For example, the FDA first licensed Connaught Laboratories' diphtheria and tetanus toxoids acellular pertussis (DTaP) vaccine, Tripedia, for children aged 15 months to seven years on August 28, 1992; on July 31, 1996, the FDA licensed Tripedia for infants at least six weeks of age. I include only the initial license date, since the product did not change. I do include combination vaccines. For example, Merck's measles, mumps, rubella, varicella (MMRV) vaccine, ProQuad, is the combination of its previously approved MMR and varicella vaccines, but the combination is a new product so I include its initial approval. Returns for vaccine manufacturers listed on a U.S. exchange as well as the value-weighted market returns come from CRSP. For firms not listed on a U.S. exchange, return data come from Datastream. The final dataset includes 75 vaccine dates before the legislation and 58 vaccine dates after the legislation.

The results, which I report in Table 1 below, suggest that vaccine manufacturers earned an average of 0.4% overall: a statistically insignificant -0.2% (p=0.6547) before the legislation, and a statistically significant 1.1% (p=0.0241) after the passage of the legislation on November 14, 1986. The 1.3% more that firms earn upon the licensing of a vaccine after the U.S. Congress passed legislation suspending product liability is statically significant (p=0.0368).

Table 1: Market reaction to announcement of new vaccine

Variable	Total sample	Before legislation	After legislation	Difference (After-Before)
CAR	0.004	-0.0016	0.0113**	0.0129**
s.e.	0.003	0.0036	0.0049	0.0061
t-stat	1.3605	-0.4491	2.3175	2.138
p-value	0.176	0.6547	0.0241	0.0368
N	133	75	58	

** Statistically signficant at the 5% level.

Although the legislation mandated increased regulatory costs, firms still enjoyed higher returns. The added costs and increased regulatory burdens might have been small for several reasons. Since U.S. state governments mandate vaccines, the demand for the product is inelastic, so increased prices from the excise tax could be passed on to the consumer or the consumer's health insurance company. Although VAERS establishes an injury reporting system that might hurt the reputation of firms, the system is passive and therefore may greatly underreport actual adverse events. Although the legislation mandates health care providers to report adverse effects, no enforcement mechanism exists to ensure that they do. The Centers for Disease Control and Prevention, which monitors VAERS, do not routinely investigate reports of injuries, so post-licensure monitoring is not enforced. In an effort to enhance the reporting system, Hinrichsen et al.

(2007) created a process to track patients with potential vaccine injuries. The research group found 20.5 events per 1,000 doses of vaccines administered. During the same time period, the number of vaccine adverse effects registered in VAERS was 0.12 per 1,000 doses, suggesting that providers report only one in 170 (= 20.5/0.12) adverse events. The passive VAERS system, therefore, probably does little harm to the reputation of vaccine manufacturers.

Finally, I examine whether vaccine prices decreased so that consumer surplus increased. The only two vaccines for which data are available from 1986 through 2014 are the inactivated polio vaccine (IPV) and the MMR. Private-sector IPV price increased over 600% from $3.80 to $27.44 per dose, and MMR increased 271% from $15.15 to $56.14. These increased exceeded the increase of the consumer price index over the period, 216%. Manning (1994) noted that prices of vaccines did not fall after the legislation; he conjectured that some uncertainty regarding liability still existed. The Supreme Court resolved the uncertainty in 2011 with its Bruesewitz v. Wyeth decision that effectively barred consumers from suing vaccine makers in civil court. See Kesselheim (2011) for more detail. If Manning's speculation was correct, prices should have fallen after 2011. However, between 2011 and 2014, the average price of vaccines increased by 10% when inflation was 5%. I can provide details upon request.

CONCLUSION

The National Childhood Vaccine Injury Act of 1986 (NCVIA) appears to be very positive for vaccine manufacturers. Before the legislation, producers faced two costs related to product liability – litigation and compensation. These costs greatly affect the market values of vaccine firms: After an appellate court upheld product liability for one firm in 1974, all vaccine manufacturers lost an average 7% of market value. The NCVIA allowed vaccine makers to vastly reduce litigation costs and to transfer the cost of compensation to consumers in the form of an excise tax. The legislation appears to have affected the market value of vaccine firms positively: After the legislation, the market rewarded the introduction of a new vaccine 1.3% higher than before. Consumers, however, do not appear to have benefited from the legislation: Producers did not lower prices, so consumer surplus did not rise.

Generalizing these results to other industries is difficult. Delitigation may only be valuable to firms that sell products, such as vaccines, that the government mandates. Otherwise, consumers may not purchase a product if they have no legal recourse after the sale.

ENDNOTES

1. I thank Jeff Wagner for very helpful and insightful suggestions on this manuscript. Participants of the 2014 New York State Economics Association Annual Conference, Loundonville, NY, also provided helpful suggestions.

2. Disclosure: I filed a claim under the U.S. National Vaccine Injury Compensation Program for my daughter. The Office of Special Masters in the U.S. Court of Federal Claims dismissed the claim on the basis of untimely filing.

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